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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,810	04/12/2004	Jennifer Lynne Reed	IL500US	5467
36577	7590	09/22/2006	EXAMINER	
JOHNATHAN KLEIN-EVANS ONE MEDIMMUNE WAY GAITHERSBURG, MD 20878			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,810	<b>Applicant(s)</b> REED, JENNIFER LYNNE	
	<b>Examiner</b> Gyan Chandra	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-7, 9-14, 23, 24-26, 29-31, drawn to a method of managing, treating or ameliorating a respiratory infection comprising administering an effective amount of an IL-9 antagonist in a human subject suffering from the respiratory infection, classified in class 514, subclass 1.
- II. Claims 4-8, 15-23, 27-28, 32-36, drawn to a method of managing, treating or ameliorating a respiratory infection comprising administering an effective amount of an IL-9 antagonist and an effective amount of at least one other therapy that is not administration of an IL-9 antagonist in a human subject suffering from the respiratory infection, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of managing, treating or ameliorating a respiratory infection comprising administering an effective amount of an IL-9 antagonist in a human subject suffering from the respiratory infection (group I) and the method of managing, treating or ameliorating a respiratory infection comprising administering an effective amount of an

Art Unit: 1646

IL-9 antagonist and an effective amount of at least one other therapy that is not administration of an IL-9 antagonist in a human subject suffering from the respiratory infection are all unrelated as they comprise distinct steps and utilize different products (for example group II comprises at least one therapy which is not IL-9 antagonist) which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I and II are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches and they are not coextensive. As such, it would be burdensome to search the inventions of Groups I and II together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

**This application contains claims directed to the following patentably distinct species:**

**Species Election for Group I and II**

Respiratory infections or diseases:

Claims 9 –14, 29, 30, and 31 list a number of respiratory infections.

Art Unit: 1646

Claims 25, 26, and 28 list a number of diseases.

The species are independent or distinct because they encompass different infections or diseases that have different etiologies and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed infection or disease for example, cystic fibrosis, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 3, 4 and 5 are the examples of a generic claim.

## **Group II**

Type of additional therapy:

Claims 15-22 and 33-35 list a number of additional therapies.

The species are independent or distinct because they include separate agents to treat a disease with different etiology, and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, for example zafirlukast, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4 and 5 are the examples of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

Art Unit: 1646

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**If Applicant elects group I, one species from the respiratory infections or diseases group must be elected to be fully responsive and If Applicant elects Group II, one species from the respiratory infections or diseases group and one species from the additional therapy group must also be elected to be fully responsive.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1646

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.  
Art Unit 1646  
8 September 2006  
Fax: 571-273-2922

  
EILEEN B. O'HARA  
PRIMARY EXAMINER